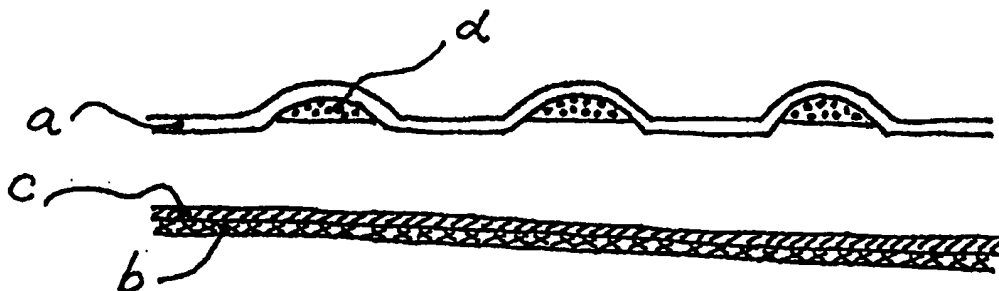




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/DK99/00037 (22) International Filing Date: 26 January 1999 (26.01.99) (30) Priority Data: 0128/98 30 January 1998 (30.01.98) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Høltedam 1, DK-3050 Humlebaek (DK). (72) Inventors; and (75) Inventors/Applicants (for US only): SAMUELSEN, Peter, Boman [DK/DK]; Bukkeballevæg 18, DK-2960 Rungsted Kyst (DK). NIELSEN, Anders, Christian [DK/DK]; Bregnerødsgade 15, 4th, DK-2200 København N (DK). (74) Common Representative: COLOPLAST A/S; Attn.: Kim Nilausen, Patent Dept., Høltedam 1, DK-3050 Humlebaek (DK).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: AN ARTICLE HAVING A SURFACE SHOWING ADHESIVE PROPERTIES

**(57) Abstract**

An article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is located in indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface enables a grading of the adhesive properties of the article.

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TITLE

An article having a surface showing adhesive properties.

FIELD OF THE INVENTION

The present invention relates to an article having a surface showing adhesive
5 properties, a method of producing such an article, a method of grading the
adhesive properties of an article having a surface showing adhesive properties,
and the use of a cover layer comprising indentations for the production of an
article having a surface showing adhesive properties wherein a further compo-
nent is located between the cover layer and the adhesive surface without being
10 in direct contact with the adhesive surface.

BACKGROUND OF THE INVENTION

Pressure sensitive adhesives intended for medical use and in particular for
adhesion to the skin of human beings must meet much more complex and
varying conditions as compared to adhesives intended to be used on well defined
15 surfaces. This is to be ascribed inter alia to the variability of the surface structure
and the surface film of the skin. The variation reflects inter alia age and races but
also influence from the local climate is vital for the behaviour of the skin. Further-
more, there may be specific requirements to adhesives to be used for certain
applications relating to treatment human beings having diseases or handicaps.
20 For instance, adhesives used for carrying ostomy bags or used for treatment of a
skin ulcer will be affected not only by the normal variations differences of the skin
but also by the secretions from the stoma or from the wound. Thus, there is a
need of an option of a local and individual grading of the adhesive properties of
an adhesive to obtain a better and more reliable performance.

25 It is known to provide adhesive surfaces with discrete areas comprising a further
component. Thus, US patent No. 4,711,781 to Nick et al. discloses a medicinal
self-adhesive plaster which comprises a continuous adhesive coating on one
surface of a carrier web, a plurality of non-permeable, separating film elements
spaced from each other on the surface of the adhesive coating and a plurality of
30 active ingredient elements containing a medication, each disposed on the

surface of one of the separating film elements whereby the medicated active ingredient is isolated from the adhesive composition.

It is an object of the present invention is to overcome the problems related to the complex demands related to effectively control the properties of a pressure
5 sensitive adhesive..

BRIEF DESCRIPTION OF THE INVENTION

The present invention relates to an article having a surface showing adhesive properties which may be adapted to the specific needs of the user.

Furthermore, the invention relates to a method of producing an article having a
10 surface showing adhesive properties which may be adapted to the specific needs of the user, to a method of grading the adhesive properties of an article having a surface showing adhesive properties, and to the use of a cover layer comprising indentations for the production of an article having a surface showing adhesive properties wherein a further component is located between the cover layer and
15 the adhesive surface without being in direct contact with the adhesive surface.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is disclosed more in detail with reference to the drawings in which Fig. 1 shows an embodiment of an article according to the invention,
Fig. 2 shows a sectional partially exploded view along the line A-A in Fig. 1, and
20 Fig. 3 shows a sectional view of another embodiment of an article according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to an article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further
25 component is located in indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface

The articles of the invention are preferably having an essentially two dimensional surface showing adhesive properties and may be in the form of a sheet or a disc. The PSA is preferably placed on a backing in the form of a film of a plastics material or the like.

- 5 The type and form of the indentations are not critical and indentations used according to the invention may e.g. be folds, grooves, ridges, bulges, bosses, bumps, lumps or bunches, or combinations thereof.

- 10 It is preferred that the amount of further component located in the indentations formed in the cover layer is below the volume of the indentations and that the further component is placed within the indentations without being in contact with the rim thereof. This preferred embodiment of the invention renders it possible to apply the further component between the adhesive surface and the cover layer without contact with the adhesive surface.

- 15 The further component may be in the form of a dot or drop or plate or disc placed in the indentations. The further component may be brought into contact with the adhesive surface, if desired, simply by pressing the cover layer against the adhesive surface using e.g. a finger which enables a controlled manner of applying the further component to the desired fraction of the adhesive surface.

- 20 Thus, it is possible, if desired, to control e.g. the adhesiveness of a surface of an article by providing a part of the adhesive surface of the article having such a surface with a second component having a different adhesiveness when applying the article. Hence, it is possible to increase the adhesiveness by applying a second component in the form of an adhesive having a stronger binding force to the substrate to which the article is to be applied or to reduce the adhesiveness
- 25 by applying a second component having a weaker binding force to a desired part of the surface of the substrate. Furthermore, it is possible to graduate the adhesiveness, e.g. so as to increase the adhesiveness along the rim of the article when applying the same to an area in which it may be subject to increased forces due to for example friction in order to reduce the risk of "rolling-up" the
- 30 edge of the article (separation of the article from the skin). This may be of

interest when applying e.g. medical dressings to parts of the body exposed to frictional forces.

It is also possible, at the discretion of the person applying the article, to decide whether or not to change the adhesive properties thereof immediately before the
5 application by simply deciding whether to elicit the application of the second component to the adhesive surface.

Such a control of the adhesive properties of a surface having an adhesive coating is neither disclosed nor indicated in US patent No. 4,711,781.

It is preferred that the indentations form a pattern which may provide for a more
10 uniform distribution over the adhesive surface and enabling a simple way of controlling the fraction of a surface to which it is desired to apply the second component.

The invention may be used in many technical fields using any appropriate adhesive. According to the invention it is preferred, and has not been proposed
15 until now, to grade adhesive properties of medical adhesives for use on human skin .

The adhesive properties of the articles according to the invention preferably are provided by a pressure sensitive adhesive (PSA).

The PSA and the further component may be constituted by a wide range of
20 different types of adhesives for instance the hydrocolloid type (thick), acrylic types, and types derived from PIB, polyurethanes, EVA-compounds, APAO's, silicones, polyvinyl ether etc. Such adhesive materials may be used for both the first adhesive and for the modifying component and the types may be chosen freely according to properties irrespectively that there may be lack of compatibil-
25 ity or there may be lack of stability as the product will be formed in situ and the application period in most instances will not be more than 14 days for medical applications.

The medical adhesive may e.g. be an adhesive comprising hydrocolloids or other moisture absorbing constituents for prolonging the time of use. The adhesive may suitably be of the type disclosed in those disclosed in GB patent specification No. 1 280 631, in DK patent specifications Nos. 127,578, 148,408, 5 154,806, 147,226 and 154,747, in EP published application Nos. 0 097 846 and 0 415 183, in SE published application No. 365,410, in WO publication No. 88/06894, in US patent specification No. 4,867,748, and in NO published application No. 157,686. Especially preferred are the adhesives disclosed in US patent Nos. 4,367,732 and 5,051,259 and DK patent specification No. 169,711.

- 10 The article according to the invention is preferably a wound dressing, a dressing for treatment of skin disorders, an ostomy appliance, an incontinence device, a breast prosthesis.

A dressing or ostomy appliance of the invention preferably has bevelled edges in order to reduce the risk of "rolling-up" the edge of the dressing or ostomy appliance reducing the wear-time and thus disturbing and prolonging the healing of 15 wounds or e.g. cracks normally healing slowly on tips of fingers or toes due to physical stress. A bevelling may be carried out discontinuously or continuously in a manner known per se e.g. as disclosed in EP patent No. 0 264 299 or in US patent No. 5,133,821.

- 20 The adhesive may be produced in any manner known per se, e.g. coating from solvent, emulsion or hot melt on release liners, films or webs of different nature.

The adhesive surface may be the free surface of an adhesive layer placed on a water impervious backing layer or film which may be of any suitable material known per se for use in the preparation of wound dressings e.g. a foam, a 25 non-woven layer or a polyurethane, polyethylene, polyester or polyamide film. The load of adhesive is suitably the same load of adhesive as is conventionally used for the production of wound dressings or ostomy appliances.

The adhesive may impart further specific properties like conductivity or insulation.

The material for modifying the adhesive surface may be adherent or non adherent, be gel like, be absorbent, contain pharmaceutical agents, contain specific bonding or moisturising or soothing agents.

The modifying component or further agent may thus be an adhesive with higher
5 or lower adhesiveness than the first adhesive depending on the desired modification of the properties. It may also be adhesives having another adhesive nature for instance a hydrophilic adhesive to be transferred to a hydrophobic adhesive or vice versa. Furthermore, the material may impart quite different properties such as antibacterial or antifungal properties to the adhesive or transfer indica-
10 tors of different sort like pH, conductive or thermal indicators. Still further, the further agent may comprise other pharmaceutically active compounds for instance for enhancing wound healing or treatment of e.g. psoriasis arthritis or other skin diseases.

Thus, an article according to the invention may be a dressing in the form of a
15 corn pad or a dressing for treatment of warts, callus or psoriasis.

On the adhesive sheet or disc is affixed a cover layer or release liner, preferably a silicone based release liner.

The cover layer or release liner used in accordance with the invention is characterised in being deformable, preferably mouldable by thermoforming. The protec-
20 tive cover or release liner will typically be siliconized thermoplastic films based on for example polyolefins such as polyethylene, polypropylene or the like. Furthermore, other types of films mouldable using stress and/or elevated temperatures may be utilised for the purpose. Examples are thermoplastic polyurethanes, polyesters, polyamides, polyvinylacetate and the like. The cover film or
25 sheet may be moulded by injection moulding for instance in form of a silicone or other elastic and siliconized material to the final shape with e.g. grooves.

When indentations are formed into the release liner, only the part of it not being subjected to moulding will be in contact with the adhesive surface when laminated together when using a gentle lamination force. For the intended use

according to the invention, the release liner must still be sufficiently deformable to enable establishment of a contact of the area of the release liner with the adhesive surface when a firm pressure is applied to the opposite side of the release liner, for instance with the pressure from a finger which implies that the
5 further component is brought into contact with the adhesive surface modifying a part of or the full surface thereof before utilising the adhesive properties of the surface, e.g. for adhering a medical device such as an ostomy appliance or a wound dressing or for adhering other articles such as a wig to human skin.

In a second aspect, the invention relates to a method of producing an article
10 having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is located in indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface wherein one or more indentations is formed in the cover layer, the further component is placed in the indentations, and the
15 cover layer is laminated with the surface showing adhesive properties using a gentle lamination force not bringing the further component into contact with the adhesive surface.

The cover layer or release liner comprising material to be transferred to the adhesive may be produced in various ways known per se, e.g. by embossment
20 or drawing or similar techniques.

A preferred method is starting from a flat thermoplastic release liner. Indentations or grooves may be processed into said release liner by stress deformation at ambient temperature but more preferable by permanent deformation due to moulding at elevated temperatures. The principles of thermo forming, e.g.
25 vacuum forming, may generally be used and additionally, pressure may be applied to one side of the release liner material according to common practice known to the skilled person. The pattern and size of the grooves or embossments or the like in the release liner may be selected according to the specific demand in use.

In each of the individual indentations an adhesive modifying material is applied in a manner known per se. One way of application is by printing for instance with tampon print or precision flexoprint. Another way of filling the indentations with modifying material is dosing this volumetrically from nozzles. The latter method
5 will be advantageous in case of transferring of greater amounts of material to the adhesive to be modified.

The most preferred method will be to carry out both operations in one step i.e. both moulding the release liner forming the specified indentations and at the same time dosing the modifying material into the indentations. This can for
10 instance be achieved by use of a printing roll in which the print transfer areas are used for the deformation of e.g. grooves in the release liner. Preferably, the release liner is preheated to a temperature suitable for easy moulding and at the same time easy transfer of the printing material, preferably using rollers for printing e.g. equivalent to the principles for flexo or tampon printing. Preferably one
15 roller is cooled in order to "freeze" the grooves formed and filled with the modifying material in order to ensure that the modifying material does not fill the grooves completely and appear at the surface of the base plane. In a similar way a roller equipped with nozzles for both moulding the release liner forming e.g. grooves and for transfer of material for modification of the first adhesive is used.
20 In the alternative, the indentations may be produced after applying the adhesive modifying second component at the intended site of the indentations.

In a third aspect, the invention relates to a method of grading the adhesive properties of an article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is
25 located in indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface, wherein the further component is brought into contact with a fraction of the surface showing adhesive properties by pressing the cover layer against the surface showing adhesive properties bringing the further component into contact with the surface
30 before removing the cover layer from the adhesive surface and applying the article.

The pressing for modifying the properties of the adhesive surface of a wound dressing or an ostomy appliance or the like may preferably be performed manually using e.g. a finger.

- In a fourth aspect, the invention relates to the use of a cover layer comprising
- 5 indentations for the production of an article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface in which cover layer a further component is located in the indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface.
- 10 In a fifth aspect, the invention relates to the use of a cover layer comprising indentations for the production of a wound dressing, a dressing for treatment of skin disorders, an ostomy appliance, an incontinence device, a breast prosthesis or other articles to be adhered to human skin, e.g. a wig or the like, having a
- 15 adhesive surface wherein a further component is located in indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface.

- In a further aspect, the invention relates to a method for providing a surface of an article with a further component modifying the properties of said surface of said
- 20 article by bringing said surface into contact with a cover layer having indentations in the first surface thereof to contact the surface of the article to be modified, said cover layer being provided with the further component placed in the indentations without being in contact with the rim thereof and said cover layer being sufficiently deformable to enable establishment of a contact between the surface
- 25 of the article to be modified and the further component by pressing at the top of the indentations from the second surface of the cover layer not in contact with the article and pressing at a desired fraction of the second surface to transfer the further component to the surface of the article.

The further component may be any of the above-mentioned. It is also considered an embodiment of the invention to apply a pattern of an adhesive to the surface of an article not being adhesive to render the surface adhesive.

- An adhesive is chosen according to the use of the article and may be any
5 adhesive being suitable for the intended use, e.g. a medical adhesive for articles to be adhered to the skin.

DETAILED DESCRIPTION OF THE DRAWINGS

The invention is disclosed more in detail with reference to the drawings showing embodiments of the invention.

- 10 Reference is made to Fig. 1 showing an embodiment of an article according to the invention comprising a backing layer or film comprising a nonwoven material **b**, an adhesive layer **c** and a cover layer or release liner **a** having embossments in the form of bulges, bosses, bumps, lumps or bunches. In the partially
sectional exploded view along the line A - A in Fig. 1 is seen that the further
15 component **d** is located in the tops of the bulges, bosses, bumps, lumps or bunches without contact with the adhesive layer when laminated using a gentle pressure.

- In Fig. 3 is shown a sectional view of another embodiment of an article according to the invention comprising a release liner having folds, grooves or, ridges in
20 which the further component is placed.

In each of the grooves one or more adhesive modifying materials may be positioned according as indicated above. The modifying materials may if desired be transferred to the surface of the first adhesive when the grooves are pressed upon as described above.

- 25 The invention is explained more in detail in the below example showing modification of the adhesion of an embodiment of a dressing according to the invention.

EXAMPLE

- A wound dressing according to the invention was prepared using a plate of a hydrocolloid adhesive having an peel adhesion of 18,4 N/25mm at a speed of 304 mm/min at ambient temperature when removed from stainless steel, said
- 5 plate having a thickness of 1000 microns and a polyester backing of a thickness of 35 microns . A 120 microns siliconised polyethylene release film was provided with grooves of a depth of 1 mm and a diameter of 5 mm and a distance between the grooves of 5 mm by deep drawing at 85 degrees C and a vacuum of 0.1 atmosphere. Another adhesive material having a peel adhesion of 47 N/25
- 10 mm at a speed of 304 mm/min at ambient temperature when removed from stainless steel was placed evenly in the form of dots having a thickness of 10 microns in the grooves of the release film. The release film was then laminated to the plate of hydrocolloid adhesive with the side of the release film comprising the second adhesive facing the plate.
- 15 After pressing on the grooves revealed an adhesive composite having a mean peel adhesiveness of 30,8 N/25 mm. Thus, it is demonstrated that it is possible to control the adhesive properties of an adhesive surface by adding a second adhesive component to a fraction of the surface.

- Thus, it is demonstrated that it is possible to control the adhesive properties of
- 20 an adhesive surface according to the invention by adding to a fraction of the surface a second adhesive component having different adhesive properties.

CLAIMS

1. An article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is located in indentations in the surface of the cover layer facing the adhesive surface without being
5 in direct contact with the adhesive surface.
2. An article as claimed in claim 1 wherein the indentions form a pattern.
3. An article as claimed in claim 1 or 2 wherein the surface showing adhesive properties and the further component are selected from the group consisting of medical pressure sensitive adhesives.
- 10 4. An article as claimed in any of claims 1 - 3 wherein the surface showing adhesive properties comprises a medical pressure sensitive adhesive, and the further component contains one or more substances such as an antifungal or antibacterial agent, an indicator such as pH, conductive or thermal indicators, or pharmaceutically active compounds such as compounds for enhancing wound
15 healing or treatment of conditions such as psoriasis arthritis or other skin diseases.
5. An article as claimed in any of claims 1 - 4, said article being a wound dressing, an article for treatment of skin disorders, an ostomy appliance, an incontinence device, or a breast prosthesis or a means or strip for fixating of a medical
20 device.
6. A method of producing an article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is located in indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface
25 wherein one or more indentations is formed in the cover layer, the further component is placed in the indentions in the cover layer, and the cover layer is laminated with the surface showing adhesive properties using a gentle lamination force.

7. A method of grading the adhesive properties of an article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is located in indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface, wherein the further component is brought into contact with and adhere to a fraction of the surface showing adhesive properties by pressing the cover layer against the surface showing adhesive properties bringing the further component into contact with the adhesive surface before removing the cover layer from the surface and applying the article.
- 10 8. Use of a cover layer comprising indentations for the production of an article having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is located in the indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface.
- 15 9. Use of a cover layer comprising indentations such as folds, grooves, ridges, bulges, bosses, bumps, lumps or bunches for the production of a wound dressing, an article for treatment of skin disorders, an ostomy appliance, an incontinence device, or a breast prosthesis having a surface showing adhesive properties and a cover layer for protecting the adhesive surface wherein a further component is located in the indentations in the surface of the cover layer facing the adhesive surface without being in direct contact with the adhesive surface.
- 20 10. A method for providing a surface of an article with a further component modifying the properties of said surface of said article by bringing said surface into contact with a cover layer having indentations in a first surface thereof to contact the surface of the article to be modified, said cover layer being provided with the further component placed in the indentations without being in contact with the rim thereof and said cover layer being sufficiently deformable to enable establishment of a contact between the surface of the article to be modified and the further component by pressing at the top of the indentions from the second surface of the cover layer not in contact with the article and pressing at a desired
- 25 30

fraction of the second surface to transfer the further component to the surface of the article.

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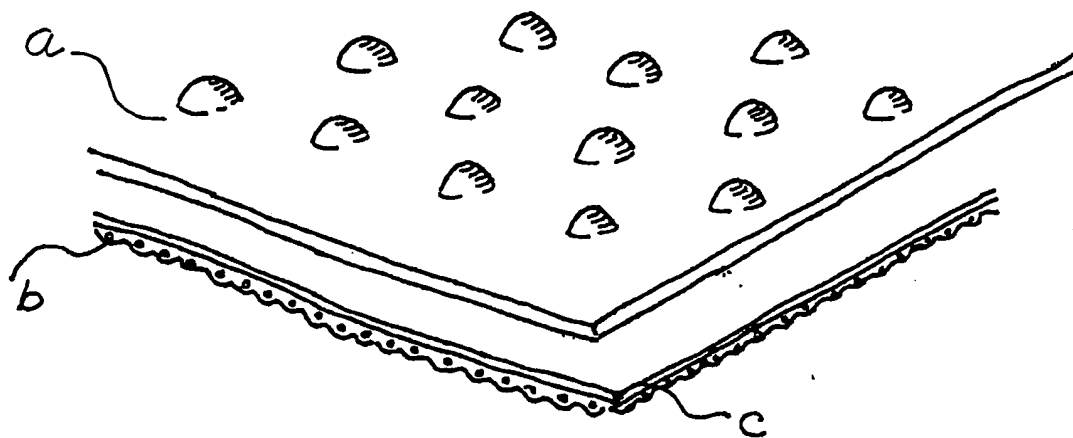


Fig. 1

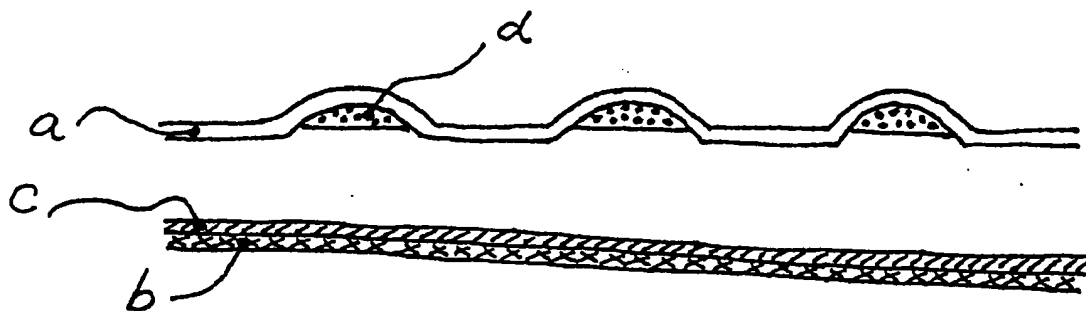


Fig. 2

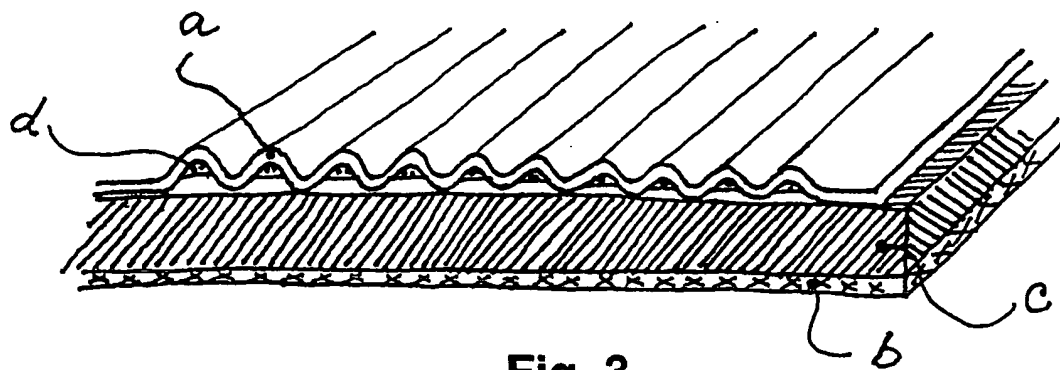


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 99/00037

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: C09J 7/02, B32B 3/26, A61F 13/02, A61L 15/58, A61M 35/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: C09J, A61F, A61L, A61M, B32B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4711781 A (ERICH NICK ET AL), 8 December 1987 (08.12.87), figure 2, abstract --	1-2,4-5
A	EP 0256893 A2 (SMITH AND NEPHEW ASSOCIATED COMPANIES P.L.C.), 24 February 1988 (24.02.88), figures 1-12, abstract --	1-10
A	EP 0117027 A1 (ELAN CORPORATION P.L.C.), 29 August 1984 (29.08.84), figures 1-4, abstract --	1-10
A	WO 9302717 A1 (SMITH & NEPHEW PLC), 18 February 1993 (18.02.93), abstract --	1-10

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search

25 May 1999

Date of mailing of the international search report

03 -06- 1999

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3763858 A (GEORGE J. BUESE), 9 October 1973 (09.10.73), figure 1, abstract -- -----	1-10

INTERNATIONAL SEARCH REPORT
Information on patent family members

03/05/99

International application No.

PCT/DK 99/00037

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4711781 A	08/12/87	AT 36118 T	15/08/88
		AT 41312 T	15/04/89
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		AU 579794 B	08/12/88
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